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Title: Significance of physician judged chronic bronchitis versus emphysema

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Body: Background: Prior data suggest chronic bronchitic symptoms in COPD are associated with poorer outcomes, but symptoms of cough and sputum are difficult to quantify. The goal of this analysis is to determine the significance of physician judged chronic bronchitis versus emphysema. Methods: Data from the placebo arms of two, one-year phase III studies of roflumilast (M2-111 & M2-112) in COPD were used to compare baseline characteristics between subjects with physician-judged emphysema vs either chronic bronchitis & combined chronic bronchitis and emphysema (CB). Cough and sputum were graded as 0 none, 1 mild, 2 moderate and 3 severe. Results: Of 1,260 subjects, 413 (32.8%) had emphysema and 847 (67.2%) had CB. CB subjects had higher FEV1% predicted, 38.0 vs 34.6 (p<0.001) and more prevalent current smoking, 42.4% vs. 31.2% (p=0.0001). Baseline SGRQ total and symptom scores were similar between CB and emphysema patients, 49.5 vs. 48.7 (p=0.46) and 56.1 vs. 53.7 (p=0.06) respectively, but SGRQ activity and impacts scores were higher in CB subjects, 64.2 vs. 67.2 (p=0.01) and 39.0 vs. 36.2 (p=0.02) respectively. In adjusted analyses, CB was not associated with more frequent exacerbations, 1.12, p=0.26. Cough and sputum scores are outlined in Table 1.

Table 1. Cough and Sputum Scores

| | Chronic Bronchitis | Emphysema | P-value |
|-----------------------|--------------------|------------|---------|
| Mean cough score | 1.20 | 0.98 | <0.0001 |
| Cough score ≥ 2 | 193 (22.8%) | 58 (14.0%) | 0.0003 |
| Mean sputum score | 1.05 | 1.12 | 0.11 |
| Sputum score ≥ 2 | 160 (18.9%) | 87 (21.1%) | 0.36 |

Conclusions: Physicians distinguished between subjects with CB who despite better FEV1, had worse SGRQ activity and impacts scores than emphysema subjects. However, subjects with physician identified

CB actually differed on baseline cough but not sputum scores.